REMARKS

In an Office Action dated February 13, 2002, claims 32-38 and 46-59, all of the claims under consideration in the subject patent application, were rejected. By amendment above, claims 32, 48, 49, and 50 have been rewritten, claims 33, 34 and 47 have been cancelled and claims 91, 92 and 93 have been substituted therefor. The above amendments should be entered at this time since they are completely in line with Applicants' prior arguments, and are being made to address issues raised in the last Office Action. The amendments thus raise no new issues that would require further consideration and/or search. The amendments are completely supported by the application as originally filed, and thus raise no issue of new matter. No additional claims are added without cancelling a corresponding number of finally rejected claims. The amendments clearly place the application in condition for allowance, or in better form for appeal by materially reducing and simplifying the issues for appeal. Accordingly, the amendments should be entered at this time.

Reconsideration of this application and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 32-38 and 46-59 were rejected under 35 U.S.C. § 112, first paragraph, on grounds of lack of enablement. Insofar as this rejection could apply to the claims, as amended, it is respectfully traversed.

Independent claim 32 as amended is directed to a diagnostic method for indirectly determining the presence of lipidic particles in cell membranes by determining the presence of anti-lipidic particle antibodies in a sample suspected of having said antibodies from an individual

suspected of suffering primary antiphospholipid syndrome or a disease associated with secondary antiphospholipid syndrome. The sample is removed from the individual and is combined with an antigen having lipidic particles immersed in a bilayer structure but not forming a part of the bilayer structure. Support for amended claim 32 can be found on page 5, lines 1-3 and page 8, lines 15-16 of the specification and claims 48, 49 and 50 have been rewritten to maintain proper dependency.

In dependent claim 93, such lipidic particles are further described as lipidic arrangements in hexagonal II or micellar phases. Support for claim 93 can be found on page 5, lines 1-3.

It is the position in the Office Action that the specification is enabling for liposomes and neoplastic cells but does not reasonably provide enablement for all lipidic particles.

Applicants submit that the method of claim 32, as amended, and dependent claims 33-38 and the kit of claim 46 and dependent claims 47-59 are directed to the indirect measurement of lipidic particles in cells by determining the presence of anti-lipidic particle antibodies in a sample.

The sample does not necessarily contain cells and enablement should be considered with respect to the anti-lipidic particle antibodies which are being detected in a sample and not to the lipidic particles themselves.

The direct determination of the anti-lipidic particle antibodies as in claim 32 as amended is an indirect measure for the presence of lipidic particles in cell membranes of the individual as such particles are defined in the specification and the antibodies are the subject of the determination in the invention as claimed.

In addition, Applicants point out that lipidic particles can form or occur in any cell membrane or liposome.

Therefore, claim 32 as amended more clearly defines the subject matter of the invention which claim is enabled by the specification as it is directed to determination of antibodies in a sample removed from a patient, which presence of antibodies is an indirect determination of the presence of lipidic particles as defined. Also, with respect to claim 46, directed to a kit for the indirect determination of lipidic particles in cell membranes in a sample, the specification is enabling for the reasons discussed above.

Claims 32-38 and 46-59 were rejected under 35 U.S.C. § 102(a) as being anticipated by Aguilar, L., et al. 1999. Applicants submit that the named inventors are the true inventors of the invention claimed in the present application and several of the named inventors are co-authors of the Aguilar, L., et al. reference. As evidence thereof, the declarations of Maria Isabel Baeza-Ramirez, Jose Leopoldo Aguilar-Faisal, Carlos Wong-Ramirez, Miguel Angel Ibanez Hernandez and Monica Lara Uc, are submitted herewith.

The accompanying declarations demonstrate that the present invention was made by the actual named inventors in the present application, not "others" as required by 35 U.S.C. 102(a). In view thereof, withdrawal of the rejection based on Aguilar, L., et al. 1999 is respectfully requested.

Claims 32-38, 46-48, 54-56 and 59 were rejected under 35 U.S.C. § 102(b) as anticipated by Ramirez et al. (1994 or 1997). Insofar as this rejection could apply to the claims, as amended, it is respectfully traversed.

Claim 32 as amended is directed to a diagnostic method comprising removing a sample suspected of having anti-lipidic particle antibodies from an individual, combining the removed sample with an antigen having lipidic particles under effective binding conditions thereby forming a mixture, to which mixture is added detectable-labeled reagent to detect the presence of anti-lipidic particle antibodies in the sample as an indirect measure of the presence of lipidic particles in the cell membranes of an individual, correlating such with immune damage in cell membranes as one of the first events in illness associated with the presence of antiphospholipid antibodies.

The prior art as cited in the Office Action does not teach or suggest the removal of a sample suspected of having anti-lipidic particle antibodies from a patient in the diagnostic method as claimed.

In addition, new claims 91 and 92 more specifically define the removed sample as in claim 32 as "antibody porter" (claim 91) which "antibody porter" may be plasma or serum (claim 92). Support for claims 91 and 92 can be found on page 16 lines 16-19.

Furthermore, with respect to independent claim 46, from which claims 47-48, 54-56 and 59 are dependent, this claim is directed to a kit comprising an indicator reagent comprising antigen having lipidic particles, a buffer solution as medium to allow effective conditions of binding said antigen to anti-lipidic particle antibodies in a sample, and a detectable-labeled reagent.

The prior art does not teach or suggest the combination as claimed in the invention directed to said kit. The prior art only teaches that lipidic particles induce the production of anti-

lipidic particle antibodies. Therefore, as not all elements in the claims are present in the prior art, the currently claimed invention is not anticipated by Ramirez et al. (1994 or 1997). Withdrawal of the rejection is respectfully requested.

Claims 32-38, 46-48, 54-56 and 59 were rejected under 35 U.S.C. § 102(b) as anticipated by Ramirez et al. (1998). Insofar as this rejection could apply to the claims, as amended, it is respectfully traversed.

Claim 32 as amended is directed to a diagnostic method comprising removing a sample suspected of having anti-lipidic particle antibodies from an individual, combining the removed sample with an antigen having lipidic particles under effective binding conditions thereby forming a mixture, to which mixture is added detectable-labeled reagent to detect the presence of anti-lipidic particle antibodies in the sample as an indirect measure of the presence of lipidic particles in the cell membranes of an individual, correlating such with immune damage in cell membranes as one of the first events in illness associated with the presence of antiphospholipid antibodies.

The prior art does not teach or suggest the removal of a sample suspected of having anti-lipidic particle antibodies from a patient in the diagnostic method as claimed.

In addition, new claims 91 and 92 more specifically define the removed sample as in claim 32 as "antibody porter" (claim 91) which "antibody porter" may be plasma or serum (claim 92).

Furthermore, with respect to independent claim 46, from which claims 47-48, 54-56 and 59 are dependent, this claim is directed to a kit comprising an indicator reagent comprising

antigen having lipidic particles, a buffer solution as medium to allow effective conditions of binding said antigen to anti-lipidic particle antibodies in a sample, and a detectable- labeled reagent.

The prior art does not teach or suggest the combination-as-claimed-in-the-invention directed to a kit. The prior art teaches the production in mice of lipidic particles by inducing such production with chloroprozamine or procainamide. The prior art further teaches the production of anti-lipidic particle antibodies. Therefore, as not all elements in the claims are present in the prior art, the currently claimed invention is not anticipated by Ramirez et al. (1998). Withdrawal of the rejection is respectfully requested.

Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

RESPECTFULLY SUBMITTED,					
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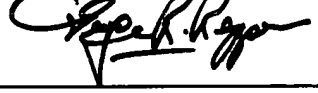
SIGNATURE				DATE	May 13, 2002
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Amended Claim 32: Version with markings to show changes made

32. (Amended) A diagnostic method for indirectly determining the presence of lipidic particles in cell membranes from a sample suspected of having anti-lipidic particle antibodies from an individual suspected of suffering primary antiphospholipid syndrome or a disease associated with secondary antiphospholipid syndrome, wherein the presence of said lipidic particles in cell membranes allows diagnosis of whether said individual is developing an illness associated with the presence of antiphospholipid antibodies though said individual does not present anti-cardiolipin antibodies, lupus anti-coagulant, anti-DNA or anti-nuclear antibodies, comprising:

a) removing a sample suspected of having anti-lipidic particle antibodies from said individual;

[a)]b) [contacting] combining the removed sample with an antigen having lipidic particles [with the sample suspected of having anti-lipidic particle antibodies from said individual], said lipidic particles being immersed in a bilayer structure but not forming a part of the bilayer structure, wherein said combining is under conditions effective to permit binding of anti-lipidic particle antibodies present in the sample to said antigen thereby forming a first mixture;

[b)]c) adding to the first mixture a detectable-labeled reagent useful for detecting binding of anti-lipidic particle antibodies to the antigen having lipidic particles thereby forming a second mixture;

[c)]d) detecting the presence of anti-lipidic particle antibodies in the sample bound to the antigen having lipidic particles in the second mixture, wherein said detection of anti-lipidic particle antibodies bound to the antigens having lipidic particles is an indirect indication of the presence of lipidic particles in cell membranes of said individual; and

[d)]e) correlating the presence of anti-lipidic particle antibodies in the second mixture with immune damage in cell membranes having lipidic particles of said individual as one of the first events in illness associated with the presence of antiphospholipid antibodies.

48. (Amended) The kit of claim [47]46, wherein said antigen comprises liposomes [have] having lipidic particles induced with one agent selected from the group consisting of divalent cations and drugs producing lupus in humans, and wherein said liposomes are in one condition selected from the group consisting of liposomes bound to microtiter plates with a high lipidic binding property and liposomes suspended in an appropriate medium.

49. (Amended) The kit of claim [47]46, wherein said antigen comprises neoplastic cells [are] bound to one solid support selected from the group consisting of micro cover glasses and microtiter plates.

50. (Amended) The kit of claim [47]46, wherein said antigen is selected from the group consisting of erythrocytes, leukocytes, and plaquettes, [are] and said antigen is suspended in an appropriate medium.